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95.  
103. The method of claim 83 wherein the pigmentation disorder is melanocytopenia.

96  
104. The method of claim 83 wherein the melanocytopenia is selected from the group consisting of vitilago and piebaldism.--

Concluded

## II. PRELIMINARY REMARKS

This response is timely filed as it is accompanied by a petition for an extension of time to file in the second month.

Support for the methods claims 79-104 is found throughout the specification and in the canceled claims 1-70. The use of stem cell factor (SCF) polypeptide to treat numerous diseases including pigmentation disorders is disclosed on page 27, lines 24 - 36. The use of stem cell factor to stimulate growth of non-hematopoietic cells is discussed on page 28, lines 3-14.

Support for the preparation and use of recited SCF fragments in claims 80-82 and 84-86 can be found variously on page 182, beginning on line 30 (1-100, 1-110, 1-120, 1-123, 1-127, 1-130, and 1-133), page 182, beginning on line 10 (1-137, 1-141, 1-145, 1-148, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-162, 1-163, 1-166, 1-168, 1-173, and 1-178), page 93, line 11 (1-164), page 183 beginning on line 7 (2-164, 5-164, and 11-164), page 183 beginning on line 34 (1-180, 1-185, 1-188, and 1-189), page 184 beginning on line 7 (1-152 and 1-157), page 93, line 12 (1-183) page 184 beginning on line 9 (1-165 and 2-165), on page 184, line 2 (1-220) and on page 185, lines 12-13.

Support for pharmaceutical compositions and formulations of SCF and including

one or more cytokines can be found on page 24, line 26 through page 30, line 29, in Example 21 (pages 156-160), Example 22 (pages 161-164), Example 23 (pages 164-168), Example 24 (pages 168-170), Example 25 (pages 170-175), and Example 26 (pages 176-179). Additional support for the combination use of SCF with other cytokines is found in Example 21 beginning on page 156. Specifically, the specification describes the synergistic effects of SCF in combination with other cytokines in stimulating cell growth and differentiation. See Example 21. Various routes of administration of pharmaceutical compositions containing SCF are disclosed on page 25, lines 31-36. *In vivo* use of PEG stabilized SCF formulations are also variously disclosed throughout the specification specifically on page 25, lines 4-11.

Finally, the applicants wish to thank the examiner for the courtesy shown the undersigned during interviews in early October 2001, wherein telephone interviews were conducted that centered on the entry of the foregoing claims in view of the restriction requirement and consolidation of co-pending application nos. 08/449,649 and 09/005,907, into the present application.

### **III. REMARKS RELATED TO THE RESTRICTION REQUIREMENT**

In a restriction requirement dated August 13, 2001, the examiner restricted original claims 1-70 into the following groups:

- I. Claims 1-12, 15, 28-30, 32, 33, 40, 41, 48-59, and 70 (stem cell polypeptides);
- II. Claims 13, 24, 16-27, 31, and 49 (DNAs encoding stem cell factor polypeptides);

- III. Claims 34-38, 61-63, 66-69 (specific methods of treatment using stem cell factor polypeptide);
- IV. Claims 42 and 43 (antibodies to stem cell factor);
- V. Claims 44-47 (process of recovery of stem cell factor);
- VI. Claim 60 (method for preparing a biologically active polymer-polypeptide adduct);
- VII. Claim 64 (method of transfecting early hematopoietic progenitor cells with a gene); and
- VIII. Claims 65 (method a transferring a gene to a mammal).

In the telephone interview between the undersigned and Examiner Bunner in early October 2001, the undersigned informed the examiner that (1) the applicants wished to pursue claims of the scope of claims 71-104, (2) that such claims were currently pending in corresponding application nos. 08/449,649 and 09/005,907, and (3) that the applicants wished to consolidate their prosecution of all three applications by introducing claims 71-104 into the present application and expressly abandoning both application no. 08/449,649 and application no. 09/005,907.

Upon disclosure of the applicants' wishes, the examiner indicated that the new claims would be considered a new and distinct group (*i.e.*, Group IX) in that they present a distinct and separate method of treatment. Therefore, by the foregoing amendment the applicants have elected new Group IX, without traverse. Further, the applicants wish to note to the examiner that application no. 08/449,649 was expressly abandoned in favor of the present application on October 10, 2001, while application no. 09/005,907, was expressly abandoned in favor of the present application on October 22, 2001.

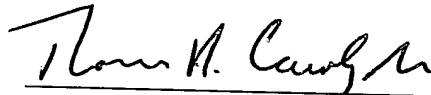
#### IV. CONCLUSION

The applicants respectfully request that claims 71-104 be examined on the merits. Should the examiner wish to discuss this submission or any matter related to the pendency of the present application, she is encouraged to contact the undersigned at the number indicated below.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN

By



Thomas A. Cawley, Jr., Ph.D.

Registration No. 40,944

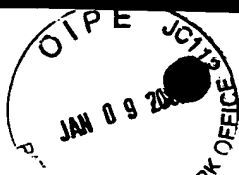
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October 31, 2001



VERSION WITH MARKINGS TO SHOW CHANGES MADE

*Claims 1-70 were canceled, without prejudice.*

*Claims 79-104 were introduced herein.*

--79. A method of stimulating growth of melanocyte precursor cells in a human, the method comprising the step of administering to the human, an amount of a human stem cell factor (SCF) polypeptide and optionally a pharmaceutically acceptable carrier.

80. The method of claim 79 wherein stem cell factor polypeptide selected is selected from the group consisting of amino acids 1-162, 1-164, and 1-165 as set out in Figure 15C, said polypeptide optionally consisting of an N-terminal methionine.

81. The method of claim 79 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-100, 1-110, 1-120, 1-123, 1-127, 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-189, 1-220, and 1-248 as set out in Figures 42A-C, said polypeptide optionally consisting of an N-terminal methionine.

82. The method of claim 79 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-152, 1-157, 1-160, 1-161, and 1-220 as set out in Figure 44A-C, said polypeptide optionally consisting of an N-terminal methionine.

83. A method of treating a pigmentation disorder in a human, the method comprising the step of administering to the human, a therapeutically effective amount of a stem cell factor (SCF) polypeptide and optionally a pharmaceutically acceptable carrier.

84. The method of claim 83 wherein the stem cell factor polypeptide is

selected from the group consisting of amino acids 1-162, 1-164, and 1-165 as set out in Figure 15C, said polypeptide optionally consisting of an N-terminal methionine.

85. The method of claim 83 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-100, 1-110, 1-120, 1-123, 1-127, 1-130, 1-133, 1-137, 1-141, 1-145, 1-148, 1-152, 1-156, 1-157, 1-158, 1-159, 1-160, 1-161, 1-163, 1-166, 1-168, 1-173, 1-178, 2-164, 2-165, 5-164, 11-164, 1-180, 1-183, 1-185, 1-188, 1-189, 1-220, and 1-248 as set out in Figures 42A-C, said polypeptide optionally consisting of an N-terminal methionine.

86. The method of claim 83 wherein the stem cell factor polypeptide is selected from the group consisting of amino acids 1-152, 1-157, 1-160, 1-161, and 1-220 as set out in Figure 44A-C, said polypeptide optionally consisting of an N-terminal methionine.

87. The method of claim 79 or 83 wherein the stem cell factor is covalently conjugated to a water-soluble polymer.

88. The method of claim 87 wherein the water-soluble polymer is polyethylene glycol.

89. The method of claim 79, or 83 wherein the stem cell factor is co-administered with at least one other cytokine.

90. The method of claim 87 wherein the stem cell factor is co-administered with at least one other cytokine.

91. The method of claim 89 wherein one or more cytokines are selected from a group consisting of IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, EPO, G-CSF, M-CSF, GM-CSF, IGF-1, and LIF.

92. The method of claim 90 wherein one or more cytokines are selected from a group consisting of IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, EPO, G-CSF, M-CSF, GM-CSF, IGF-1, and LIF.

93. The method of claim 79 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

94. The method of claim 79 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

95. The method of claim 79 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

96. The method of claim 79 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

97. The method of claim 79 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

98. The method of claim 83 wherein the pharmaceutically acceptable carrier is suitable for topical delivery.

99. The method of claim 83 wherein the pharmaceutically acceptable carrier is suitable for oral delivery.

100. The method of claim 83 wherein the pharmaceutically acceptable carrier is suitable for parenteral delivery.

101. The method of claim 83 wherein the pharmaceutically acceptable carrier is suitable for pulmonary delivery.

102. The method of claim 83 wherein the pharmaceutically acceptable carrier is suitable for nasal delivery.

103. The method of claim 83 wherein the pigmentation disorder is melanocytopenia.

104. The method of claim 83 wherein the melanocytopenia is selected from the group consisting of vitilago and piebaldism.--